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In the News

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LASAGNA COMMITTEE ISSUES FINAL REPORT

The presidentially-commissioned report by the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS, (the Lasagna Committee), advocates reimbursement and insurance coverage policies that the ACCC has been promoting for a considerable period of time. ACCC Executive Director, Lee Mortenson, testified twice before the Committee regarding the current vagaries of insurance coverage for state-of-the-art cancer treatment. In agreement with the Association's contentions, the Committee's final report strongly advocated that the judgment of the attending physician and medical compendia should dictate insurers' reimbursement policies, not FDA approval.

The Committee's report stated that "insurance coverage of investigational drugs, and of marketed drugs prescribed for unlabeled indications, should rely primarily on their approval by expert government agencies for therapeutic use (such as the NCI approval of Group C cancer drugs and the FDA approval of drugs under treatment INDs) or their status in authoritative medical compendia (such as the three that were intended for use under the Medicare Catastrophic Act of 1988)." In its report, the Committee contended that "usage approved by such expert authority is more valid as a basis for reimbursement than FDA approval of an NDA, since NDA approval may not as yet have been sought by the specific manufacturer, and in fact for some drugs or uses might never be sought." Furthermore, the report said that "coverage should be identical under Medicare, Medicaid, and private insurance, whether they are paid for directly or under a prospective payment system, and should not vary from region to region or carrier to carrier."

The Committee also contended that coverage should be automatic once the usage is approved in one of the compendia. "Individual carriers should have no discretion with respect to such matters, and this policy should apply equally to inpatient services, outpatient drugs administered by a physician, and self-administered prescription drugs if that benefit becomes effective. For indications or drugs that are approved by experts but have not yet found their way into authoritative compendia," the report stated that "an independent advisory committee may be needed to authorize reimbursement of unapproved drugs or unapproved uses."

The report referred to the legal decision in *Weaver v. Reagan*, in which Missouri Medicaid could not lawfully deny coverage of AZT to AIDS patients because, even though the drug was still investigational and not yet approved by the FDA, it was determined to be medically necessary by the attending physician. In agreement with that decision, the report said that "the touchstone of drug coverage should be the medical judgment of the attending physician."

Finally, the Committee's report also stated that "coverage for the hospital, physician, and other medical care costs for patients involved in cancer and AIDS clinical trials should take cognizance of the fact that peer-reviewed, scientifically sound trials provide state-of-the-art treatment for patients desperately needing such treatment but for whom currently available drugs are ineffective. For such patients, scientifically meritorious investigational drug therapy is the best available treatment and together with ancillary medical care should be covered by all health insurance agencies."

Copies of the full report, which addresses 19 other issues, including expedited review by the FDA, wider access to investigational new drugs, surrogate endpoints, the role of institutional review boards in phase I and II clinical trials, and treatment INDs, is available from the NCI.

HOUSE COMMITTEE URGES CONTROLS ON BIOMEDICAL RESEARCH

Despite the decision by the Department of Health and Human Services last December to drop proposed conflict-of-interest guidelines that would have strictly limited the financial interests of researchers who receive government grants, a new report has been issued that is highly critical of the problems posed by scientists who fail to live up to accepted research standards. The report, issued by the House Government Operations Committee, urges the need for tighter legal controls on federally-funded biomedical research. Charging that universities and the National Institutes of Health do not adequately investigate misconduct and conflicts of interest on the part of researchers, the report cites a number of cases of scientific fraud and falsification of data.

Although the Public Health Service (PHS) is drafting new conflict-of-interest regulations, Rep. Ted Weiss (D-NY), chairman of a subcommittee on human resources and intergovernmental relations, wrote in an addendum to the report that those PHS guidelines are weaker than the guidelines that were withdrawn, and he has suggested that if the PHS doesn't strengthen the guidelines, "Congress should enact legislation to achieve that goal."

According to a spokesman for the PHS, no timeframe has been established for completion of the conflict-of-interest regulations. However, the proposed guidelines will be published in the *Federal Register*.

MAMMOGRAPHY SURVEY POINTS OUT PUBLIC EDUCATION NEEDS

The number of women, age 40 and older, who have had at least one mammogram has risen sharply over the past two years, from 37 percent in 1987 to 64 percent in 1990, according to a survey by the Jacobs Institute of Women's Health and the National Cancer Institute. However, despite that rise, the survey reports that women are still not getting mammograms as often as they should. Only 31 percent of the 980 women surveyed are following guidelines recommending regular mammograms once a woman reaches the age of 40.

At a news conference announcing the survey results, Douglas Marchant, M.D., Professor of Surgery at Tufts New England Medical Center, contended that "doctors have to do a better job of recommending that women get mammograms," noting that almost half of the women who "never had a mammogram said their doctor had not recommended it." On the other hand, Marchant said that "nearly three-quarters of the women who had a

mammogram did so because their doctors recommended it. "Other survey findings included:.

- ☐ Only 24 percent of women age 65 and over follow the guidelines for mammography.
- ☐ One-third of the women who have had one mammogram don't believe they need a second if the first one shows no problems
- ☐ Women with higher income levels are more likely to get mammograms. Seventy-seven percent of women with household incomes of more than $50,000 per year have had a mammogram, in contrast to 60 percent of women with household incomes under $25,000 per year.
- ☐ Forty percent of the women who have never had a mammogram have not scheduled one because of a lack of family history of the disease.

REIMBURSEMENT LEGISLATION ENACTED IN NY; VETOED BY CA GOVERNOR

Legislation amending New York's insurance law and mandating coverage for the off-label use of antineoplastic drugs was signed into law by Governor Mario Cuomo in September, but a more comprehensive piece of legislation, mandating coverage not only for off-label drug uses but investigational therapy and related medical costs,was vetoed by the governor of California in October.

As a result of the New York legislation, health insurers cannot deny coverage for the off-label use of antineoplastic drugs and their administration provided that the drug in question has been prescribed for such use in one of three reference compendia (*Drug Evaluations* by the AMA, *Drug Information* by the American Hospital Formulary Service, and *USPDI* by the U. S. Pharmacopeia). The legislation applies to every insurer in the state that provides coverage for prescribed drugs.

The California legislation, developed by the Life AIDS Lobby in Sacramento, successfully passed the Assembly and Senate only to be vetoed by Governor Deukmejian, who was concerned about the cost implications of the bill. According to Alan Lofaso, Legislative Advocate for Life AIDS Lobby, "next year will be a much better year for seeking passage of the bill, because California will have a new governor." To that end, the group is currently seeking support for the legislation from gubernatorial candidates, including Diane Feinstein, former mayor of San Francisco. ■